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| 10/070,181 | 07/08/2002 | Jeffrey L. C. Wright | 86450 | 3116 |

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WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

| EXAMINER | |
|---|---|
| PUTTLITZ, KARL J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1621 | |

DATE MAILED: 09/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/070,181 | WRIGHT ET AL. | |
| | Examiner | Art Unit | |
| | Karl J. Puttlitz | 1621 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *08 July 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-37* is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Objections*

Claims 8-13, 21-25, 32, 34, 36 and 37 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend on another multiple dependant claim See MPEP § 608.01(n).

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14, 15, 26, 27, 28, 29, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the omega-3 fatty acids of claim 3 and particular phytosterols listed in the application does not reasonably provide enablement for all omega-3 fatty acids and sterols. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

"The standard for determining whether the specification meets the enablement requirement [in accordance with the statute] was cast in the Supreme Court decision of *Mineral Separation v. Hyde,* 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.,* 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation.").

In the instant case the rejected claims cover all omega-3 fatty acids and sterols. Based on the above standards, the disclosure must contained sufficient information to enable one skilled in the pertinent art to use this invention without undue experimentation. See M.P.E.P. 2164.01. Given the scope of the claims, it does not.

The specification and the examples do not provide sufficient disclosure that would provide one of ordinary skill guidance to practice the invention, given the infinite amount of all possible permutations of omega-3 fatty acids and

sterols. In this regard, the disclosure does teach those of ordinary skill how to select appropriate omega-3 fatty acids and sterols with the desired function of lowering cholesterol and triglyceride levels in the bloodstream., where the instant specification only describes broad geni of omega-3 fatty acids and sterols.

The examiner understands that there is no requirement that the specification disclose every possible embodiment if there is sufficient guidance given by knowledge in the art (See M.P.E.P. § 2164.05(a) "[t]he specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).").

However, the instant case goes beyond what is known in the art, because the specification does not offer any guidance on how one of ordinary skill would go about practicing the invention for all omega-3 fatty acids and sterols with the desired function of lowering cholesterol and triglyceride levels in the bloodstream, which would constitute undue experimentation.

Applicant is reminded of the heightened enablement for chemical inventions. Specifically, the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. *In re Fisher*, 427 F.2d 833, 839, 166

USPQ 18, 24 (CCPA 1970). The "amount of guidance or direction" refers to that information in the application, as originally filed, that teaches exactly how to make or use the invention. The more that is known in the prior art about the nature of the invention, how to make, and how to use the invention, and the more predictable the art is, the less information needs to be explicitly stated in the specification. In contrast, if little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. [I]n the field of chemistry generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim. This will especially be the case where the statement is, on its face, contrary to generally accepted scientific principles. Most often, additional factors, such as the teachings in pertinent references, will be available to substantiate any doubts that the asserted scope of objective enablement is in fact commensurate with the scope of protection sought and to support any demands based thereon for proof. [Footnote omitted.]

Here, the requirement for enablement is not met since the claims go far beyond the enabling disclosure. Accordingly, base on the forgoing, the rejected claims are *prima facie*, non-enabled for their full scope.

Claims 14, 15, 26, 27, 28, 29, 36, and 37 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims cover all esters of all omega-3 fatty acids and sterols.

To satisfy the written-description requirement, the specification must describe every element of the claimed invention in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the claimed invention at the time of filing. *Vas-Cath*, 935 F.3d at 1563; *see also Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention"); *In re Gostelli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989) ("the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed").

For chemical and biotech inventions, "[a]n adequate written description of a DNA ... 'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). Courts have stated that "[i]n claims involving [non-genetic] chemical materials, generic

formulae *usually indicate with specificity what the genericclaims encompass*. One skilled in the art can distinguish such a formula from others and *can identify many of the species* that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus." *Eli Lilly & Co.*, 119 F.3d 1568, (emphasis added). There is no such specificity here, since the claims merely recite all omega-3 fatty acids and sterols.

The terms "omega-3 fatty acids" and "sterols" contain almost no information by which a person of ordinary skill in the art would understand that the inventors possessed the entire scope of the claimed invention. At best, it simply indicates that one should test an infinite number of compounds in order to see if they posses the desired function of lowering cholesterol and triglyceride levels in the bloodstream.

Here the claims recite a copolymer of 2,2-dinitropropyl acrylate and 2,2-dinitrobutyl acrylate. However, the specification fails to describe any parameters of the claimed polymer, such as molecular weights, or other monomers that may be used in order to achieve the desiredenergetic binder. While the need for some experimentation is by no means necessarily fatal, "reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.". Id. This reasonable detail is lacking in the captioned application. Specifically, the specification provides little guidance in the way of selecting a particular copolymers, or even of narrowing the range of molecular weights, or

co-monomers in order to find a suitable copolymer with the desired characteristics as an energy binder.

Nowhere does the specification point to any particular language in the application setting forth how to select those copolymers that would be likely candidates of the claimed formula. While it is true that a patent need not disclose that which is already well known in the art in order to be enabling, *see, e.g., Hybritech Inc. v. Monoclonal A* (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987), far more is needed to enable the claimed copolymers. The specification fails to identify any suitable copolymers, or explain how one can discover such a copolymer which has the desired attributes of a an energy binder.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 does not further limit claim 1.

Claim 15 states that the omega-3 fatty acid is derived from fish oil. It is unclear exactly what compounds Applicant intends by this language since the structure of compounds "derived from fish oil" is indefinite.

Claims 26 and 28 are use claims which do not recite specific steps in the lowerinf of cholesterol and triglyceride levels, or for the manufacture of a food stuff. See vM.P.E.P. § 2173.05(q) ("Attempts to claim a process without setting

forth any steps involved in the process generally raises an issue of indefiniteness under 35 USC 112, second paragraph. For example, a claim which read: "A process for using monoclonal antibodies of claim 4 to isolate and purify human fibroblast interferon." was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986). . . . Although a claim should be interpreted in light of the specification disclosure, it is generally considered improper to read limitations contained in the specification into the claims. See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975), which discuss the premise that one cannot rely on the specification to impart limitations to the claim that are not recited in the claim. ").

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, 7, 9, 14-16, 20, 22, and 26-28 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 897970, as evidenced by**

**counterpart U.S. Patent No. 6,160,886 to van Amerongen et al. (van Amerongen).**

This patent teaches a process for the preparation of stanol fatty acid esters mixtures by inesterification of stanol fatty acid esters starting material is new and comprises reacting (at least 50%) saturated fatty acid groups of starting material with a source of at least one fatty acid moiety containing at least 35% (especially 45%) polyunsaturated fatty acid (PUFA) groups.

The product is incorporated into foods, See column 1, lines 58-64.

The products have blood cholesterol lowering effects. See column 4, lines 6-14.

The foregoing anticipates the claims within the meaning of section 102.

**Claims 1-3, 7, 9, 14-16, 20, 22, and 26-28 are rejected under 35 U.S.C. 102(a) as being anticipated by EP 1004595 (EP 594).**

This reference teaches phytosterols that are esterified with polyunsaturated fatty acids. The products are useful in foods. See claim 7.

The products are useful in lowering blood cholesterol levels. See paragraph 0025.

The foregoing anticipates the claims within the meaning of section 102.

**Claims 1-3, 9, 14, 15, 16, 22 and 26-28 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,502,045 to Miettinen et al. (Miettinen).**

This patent teaches fatty acid esters of sitostanol. See column 3, lines line 7-16. The product is useful as food to lower cholesterol. See paragraph bridging columns 4 and 5.

The foregoing anticipates the rejected claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-6, 8, 10-13, 17-19, 21 and 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over each of Amerongen or EP 594.

The claims cover specific omega-3 fatty acids or sterols not explicitly disclosed by Amerongen or EP 594 so as to amount to anticipation (See M.P.E.P. § 2131: "[t]he identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226,

1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).). However, based on the above, the applied references teaches the elements of the claimed invention with sufficient guidance, particularity, and with a reasonable expectation of success, that the invention would be *prima facie* obvious to one of ordinary skill (the prior art reference teaches or suggests all the claim limitations with a reasonable expectation of success. See M.P.E.P. § 2143).

Claims 29-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miettinen in view of Lo et al., JAOCS, 60, 4, 1983 (Lo).

The claims are drawn to a process for preparing the nutritional supplement, which comprises reacting a sterol with an omega-3 fatty acid, or an ester thereof, in the presence of a base.

Miettinen teaches esterification of stanols and fatty acids. The difference between the process disclose by Miiettinen and the process covered by the rejected claims is that Miettinen fail to disclose the presence of a base. It is for this proposition that the examiner joins Lo. Specfically, Lo teaches the interesterification of fatty acids with sodium methoxide.

One of ordinary skill would have been motivated to modify Miettinen to include a base catalyst since Lo teaches that theses catalyst are useful for the

esterification of fatty acids. Therefore the rejected claims are prima facie obvious in view of the combination of Miettinen and Lo since these references suggest the elements of the claims with a reasonable expectation of success.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karl J. Puttlitz whose telephone number is (571) 272-0645. The examiner can normally be reached on Monday-Friday (alternate).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Karl J. Puttlitz
*Assistant Examiner*

E/ B
ACTING FOR
Johann R. Richter, Ph.D., Esq.
Supervisory Patent Examiner
Biotechnology and Organic Chemistry
Art Unit 1621
(571) 272-0646